

		GTEx Work Instruction for Green Kit Receipt and Shipping	
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1. PURPOSE

This work instruction provides the specific steps necessary to pack and ship the CBR-issued caHUB/GTEx Whole Brain, Brain Stem and Hair Collection (the green kit).

The procedure section is divided into four subsections: the kit receipt at the Biospecimen Source Site (BSS); the alert of pending collection; packing instructions; and shipping instructions.

2. ENVIRONMENTAL HEALTH & SAFETY

2.1. Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association (IATA)/ International Civil Aviation Organization (ICAO) regulations.

3. PROCEDURE

Kit Receipt at the BSS

3.1. Contents correspond to supplies shown in Figure 1.

3.1.1. 1 insulated UN3373 fiberboard box with outer green kit label and external ID label

3.1.2. 1 plastic bucket with O-ring and hinge-pin lid (labeled with sequence number 0011 and Biohazard)

3.1.3. 3 absorbent sheets

3.1.4. 1 – 4 lb freezer brick, which goes inside the plastic bucket

3.1.5. 4 – 3 lb freezer bricks that are inside a bubble sleeve or a ziplock bag

3.1.6. 1 circular moldable foam insert with brain stem cut-out so the brain will sit on flat base in bucket (not shown in Figure 1).

3.1.7. 1 rectangular foam strip that surrounds the brain

3.1.8. 2 circular foam inserts

3.1.9. 2 cardboard inserts

3.1.10. 5 large sealable plastic bags for ice to pack the head

3.1.11. 2 leak proof biohazard bags to house the brain

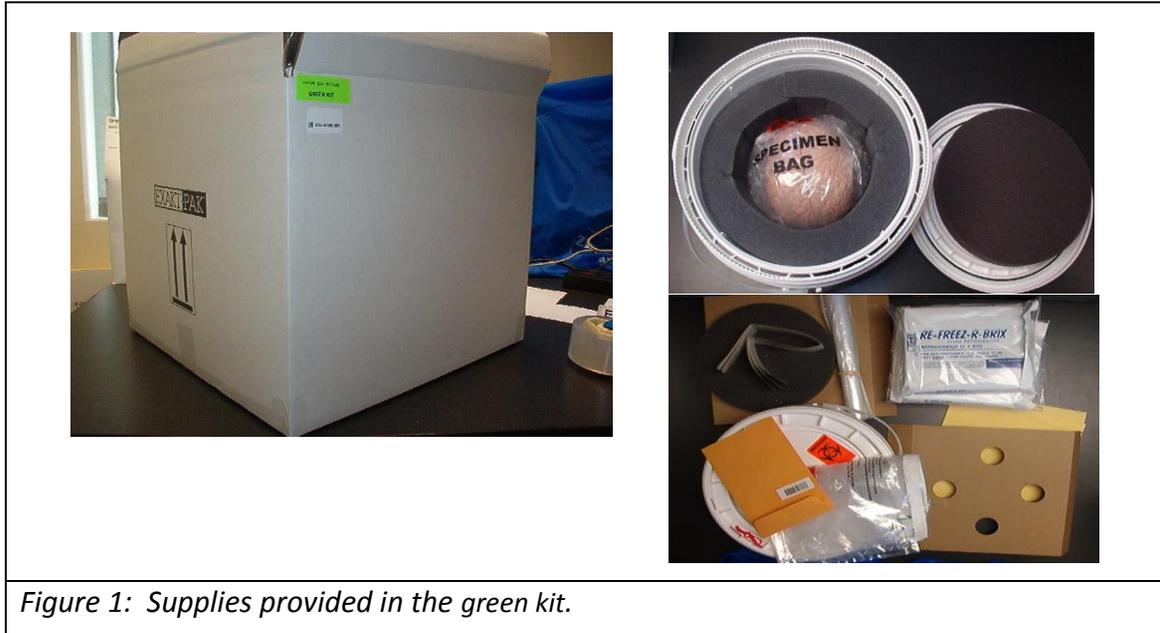
3.1.12. Styrofoam™ insulation including 4 sides, a bottom and a lid (not shown in Figure 1)

3.1.13. **GTEx Discrepancy Checklist for Green Kit (OP-0001-W2-F1)** with bag for paperwork (not shown in Figure 1).

3.1.14. Three 24-in tape strips to seal the fiberboard box (not shown in Figure 1).

3.1.15. Unlabeled small manila envelope

3.1.16. Small glassine envelope with sequence 0014.



Alert of Completed Collection

- 3.2. Timeline of alert to the Brain Bank
 - 3.2.1. Immediately upon completion of procurement.
- 3.3. Method of alert to the Brain Bank: Phone and **Shipping Vendor alert**
 - 3.3.1. Immediately contact the Brain Bank by phone.
 - 3.3.2. Use the following instructions for the email template for correspondence to Brain Bank:
 - 3.3.2.1 Enter all pertinent information/choose correct information in drop down menus into the Shipping Vendor system.

NOTE: Once a BSS goes online to setup a shipment, the system will prompt the user to enter a Kit reference number. This should be the GTEX case # and Kit #. (Example: GTEX Case ID:0000XXX/Kit-0XXX).
 - 3.3.2.2 Print the shipping form twice (4 copies). Courier will sign, date and time one copy and return to BSS. The other 3 copies go with the courier with the shipment.
 - 3.3.2.3 When the pickup card is received in the Shipping Vendor system, an alert will be sent to the appropriate individuals at the Brain Bank and CBR
- 3.4. **Change in Delivery Status Alert Instructions**
 - 3.4.1. If a collection alert was forwarded to the Brain Bank and it is later determined, for any reason, the shipment will be delayed, cancelled, or there is a mistake in information on the printed forms, call the Shipping Vendor IMMEDIATELY!
 - 3.4.2. The Shipping Vendor will update any recipients with any delays, re-routes, etc.
 - 3.4.3. An alert email will be sent to the appropriate individuals at the Brain Bank and CBR.

Packing Instructions

- 3.5. Packers and shippers of the green kit must be certified to ship IATA class 6.2 material.
- 3.6. Upon kit receipt, verify contents of kit using the list above (3.1).
- 3.7. If the kit is incomplete or broken
 - 3.7.1. Complete **GTE_x Discrepancy Checklist for Green Kit (OP-0001-W2-F1)**.
 - 3.7.2. Report defective kits to kit supplier.
 - 3.7.3. CBR will follow-up with an action for resolution.
- 3.8. On the day the kit is used, complete the following steps:
 - 3.8.1. Arrange for shipment pick-up with the Shipping Vendor so the sample is picked up as soon as the brain, brain stem, and hair have been recovered. **THIS SHIPMENT MUST LEAVE THE BSS AS SOON AS POSSIBLE AFTER THE COLLECTION IS COMPLETED.**
 - 3.8.2. Using the labels found on the label sheet in the overpack kit; transfer the full GTE_x specimen labels to the plastic bucket and manila envelope.
 - 3.8.3. Whole Brain and Brain Stem Packing: Follow Figures 2 to 14 for packaging instructions.
 - 3.8.4. Hair Packing: The hair sample placed inside the glassine envelope is then placed inside a manila envelope. Follow instructions for hair packing (Figure 12).

Figure 2: View at the bottom of the inside shipping package. There is a cardboard insert and a round foam disk for the plastic bucket to sit on to reduce vibration during shipping.



Figure 3: Place four -20 °C frozen 3-lb freezer bricks individually wrapped in bubble plastic along the outside walls of the shipping container.



Figure 4: Place one -20 °C frozen 4-lb freezer brick in plastic bucket.



Figure 5: Place foam with stem cut-out over 4-lb freezer brick.

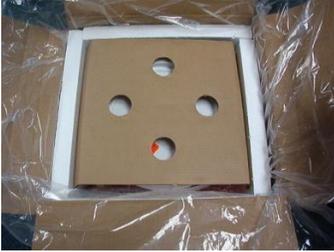


Figure 6: Place whole brain and brain stem into a leak-proof biohazard bag. Remove as much of the air as possible to prevent brain from moving during shipment.

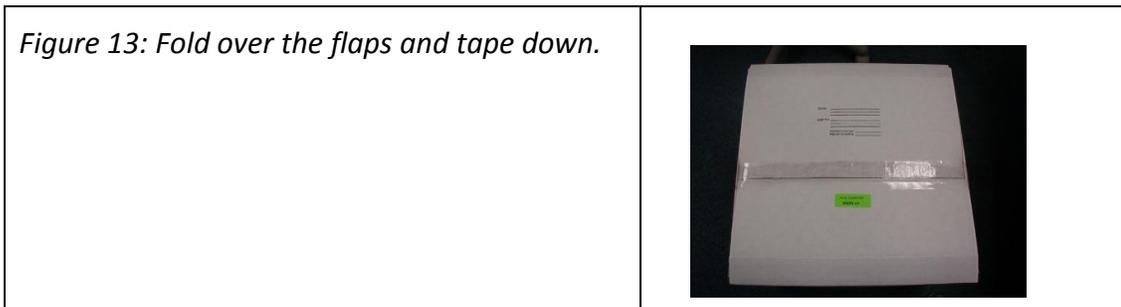


Figure 7: Place bagged whole brain and brain stem into a second leak-proof biohazard bag. Again, remove as much of the air as possible.



<p><i>Figure 8: With brain stem down, carefully slide brain into foam insert so the stem is in the foam cutout.</i></p>	
<p><i>Figure 9: Encircle the whole brain with the rectangular foam strip.</i></p>	
<p><i>Figure 10: Place a foam insert over the whole brain. Close the bucket. Take care not to catch the large side icepacks in the threads of the lid while closing.</i></p>	
<p><i>Figure 11: Add the cardboard insert so that it is inverted over the plastic bucket.</i></p>	
<p><i>Figure 12: Place the outer Styrofoam™ lid on top. Insert the following 3 items:</i></p> <ol style="list-style-type: none"> 1. Completed Chain of Custody Form (OP-0002-F1) 2. Completed GTE_x Tissue Data Collection Form 3. Manila envelope with the hair sample is placed on top 	

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3.8.5. Email a copy of the **Chain of Custody Form (OP-0002-F1)** to GTEEx staff.

Shipping Instructions

3.9. Waiting for Shipment

3.9.1. If the courier pick-up is anticipated to be more than one hour from the time the kit is packed, please hold in a cold room at a temperature of 4°C until the courier arrives.

3.10. Verify the pick-up of the green kit by the courier.

3.11. Brain Bank Confirmation of Receipt

3.11.1. The BSS should expect an email confirmation of receipt from the Brain Bank.

4. REFERENCES

4.1. Chain of Custody Form, (OP-0002-F1).

4.2. GTEEx Tissue Procurement, SOP (PR-0004)

5. ATTACHMENTS

5.1. GTEEx Discrepancy Checklist for Green Kit, (OP-0001-W2-F1)